

### REMARKS

Claims 1, 5 and 10 have been amended to indicate that the intravaginal ring is a "medicated" intravaginal ring. Support for this amendment can be found at, for example, page 1, line 5.

Claims 1, 5, 6 and 10 have been amended to change the language "comprising" to "consisting of" with respect to the package or sachet components.

Claim 6 has been amended to set forth the full name for PET as suggested by the Examiner.

Claim 10 has been amended to specify that method is to prevent the active substances present in the ring from leaking to the environment. Support for this amendment can be found at page 1, lines 12-13.

It is submitted that these amendments do not constitute new matter, and their entry is requested.

Claims 6 and 10 were rejected under 35 U.S.C. §112, second paragraph for being indefinite. It is submitted that the amendments to claims 6 and 10 obviate this rejection. Withdrawal of this rejection is requested.

Claims 1-3 and 8 were rejected under 35 U.S.C. §103(a) as being obvious over Gero (US 4,692,143) in view of FR 2748994. A complete copy of this French patent (beyond the abstract cited by the Examiner) is attached for the convenience of the Examiner. The Examiner contends that it would have been obvious to use a reclosable package for the vaginal sponge of Gero in view of the teaching in FR 2748994 to used a reclosable package for a contraceptive. The Examiner also contends that the loop attached to the sponge of Gero reads on Applicants' intravaginal ring. It is submitted that the Examiner is in error in this rejection.

The objective problem of the subject invention is packaging an intravaginal ring comprising active substances in such a manner that the active substances do not leak into the environment. This problem is solved by the subject invention, i.e. by an aseptic package as described in claim 1 having three layers (one of which is a barrier layer) and a reclosable strip.

Gero does not relate to a packaging problem. Gero discloses a vaginal sponge comprising a spermicidal composition which is packaged in a sealed foil packet of two layers (without a barrier layer and without a reclosable strip) in order to remain sterile and uncontaminated at all times (column 1, line 58-59, column 2, lines 11-12). Gero is not concerned with packaging the sponge in order to prevent leaking of the spermicidal material from the sponge into the environment. In addition, the present claims are directed to a package for a "medicated intravaginal ring." The loop on Gero's sponge does not read on a "medicated intravaginal ring."

The deficiencies of Gero are not remedied by FR 2748994. FR 2748994 describes a package for disposal of a used condom ("*preservatif*" in French means condom). The package layers are not specified and the closing flap is certainly **NOT** a reclosable strip. In fact, the closing flap can only be closed once: "*le cellage definitif*" (page 3, line 4), because it contains an adhesive (4), as shown in the abstract cited by the Examiner. Because the flap contains an adhesive, it is not a reclosable strip but instead is only closed one time after use of the condom. Thus, Applicants submit that FR 2748994 has no relevance whatsoever to the subject invention.

Because FR 2748994 is concerned with a package that can be sealed, i.e., closed, after use of the condom and cannot be opened and closed by a reclosable strip, there is no incentive to combine Gero with FR 2748994.

Even if, *in arguendo*, there was some incentive to combine these references, a skilled artisan would certainly not arrive at the package of the subject invention because neither of the cited references discloses a package with the limitations set forth in the claims, namely a package comprising a laminate and a reclosable strip in which the laminate consists of a layer of sealable material, a barrier layer and a damage protective layer.

Thus, Gero in view of FR 2748994 does not render claims 1-3 and 8 obvious. Withdrawal of this rejection is requested.

Claims 1-4, 6 and 8 were rejected under 35 U.S.C. §103(a) as being obvious over Igarashi (US 4,997,653) in view of JP 05-154170 and further in view of FR 2748994. The Examiner

contends that it would have been obvious to use the package of JP 05-154710 which may be resealable as taught by FR 2748994 for packaging the vaginal ring of Igarashi. It is submitted that the Examiner is in error in this rejection.

Igarashi describes a danazol-containing ring which can be packaged with heat-sealable aluminum packaging material. Igarashi does not specify the package, it does not specify the layers, it does not specify the manner of closing the package nor does it relate to the problem of leakage of active substances from the ring into the environment.

These deficiencies are not remedied by JP 05-154170 alone nor in combination with FR 2748994. JP 05-154170 relates to packaging of an (unspecified) contraceptive, having **four** layers which is useful in packaging machinery. This disclosure, as it relates to packaging machinery, most likely involves condoms (which are a non-hormonal form of contraception). This can be further substantiated by the sentence in the translation which reads *"Moreover, if it is at the time of use of a contraceptive, from every direction, a package bag can be torn easily and can be opened"*. JP 05-154170 does not relate to reclosable packages and does not relate to intravaginal rings containing active ingredients, let alone to the problem of leakage of active substances from the ring into the environment. In addition, JP 05-154170 does not disclose a package with the claimed limitations, namely a package comprising a laminate and a reclosable strip in which the laminate consists of a layer of sealable material, a barrier layer and a damage protective layer

As discussed above, FR 2748994 relates to the packaging of used condoms and does not disclose a package with the claimed limitations, namely a package comprising a laminate and a reclosable strip in which the laminate consists of a layer of sealable material, a barrier layer and a damage protective layer.

Because FR 2748994 is concerned with a package that can be sealed, i.e., closed, after use of the condom and cannot be opened and closed by a reclosable strip, there is no incentive to combine Igarashi or JP 05-154170 with FR 2748994. Furthermore, because, JP 05-154170 and FR

Application Serial No. 09/555,459  
Amendment dated 14 January 2005  
Reply to Office Action mailed 14 October 2004

2748994 both relate to a distinct field, namely condoms, there was no incentive to combine Igarishi with either JP 05-154170 and FR 2748994.

Even if, *in arguendo*, there was some incentive to combine these references, a skilled artisan would certainly not arrive at the package of the subject invention because none of the cited references discloses a package with the limitations set forth in the claims, namely a package comprising a laminate and a reclosable strip in which the laminate consists of a layer of sealable material, a barrier layer and a damage protective layer.

Therefore, Igarishi in view of JP 05-154170 and further in view of FR 2748994 does not and cannot render claims 1-4, 6 and 8 obvious. Withdrawal of this rejection is requested.

Claims 1-5 and 7-10 were rejected under 35 U.S.C. §103(a) as being obvious over Igarashi (US 4,997,653) in view of JP 7-223653. The Examiner contends that it would have been obvious to use the laminated bag of JP 7-223653 for the vaginal ring of Igarashi. It is submitted that the Examiner is in error in this rejection.

In reply, as discussed above, Igarashi describes a danazol-containing ring which can be packaged with heat-sealable aluminium packaging material. Igarashi does not specify the package, it does not specify the layers, it does not specify the manner of closing the package nor does it relate to the problem of leakage of active substances into the environment.

JP 7-223653 relates to packing bags comprising a laminated body with a zip for, e.g., medical products such as compresses and ointments. JP 7-223653 does not relate to intravaginal rings, let alone intravaginal rings comprising active ingredients. JP 7-223653 also does not relate to problem of leakage of active substances from such a ring into the environment. It relates to a different problem, namely to provide air tightness so that the contents of a bag do not dry out, evaporate, moisturize, degenerate, volatilize or leak odour (see page 5 of the translation). The bag of JP 7-223653 appears to have at least four layers (see page 8 of translation).

Even if, *in arguendo*, one were to use the bag of JP-223653 which has at least four layers for the danazol-containing ring of Igarishi, one would still not arrive at the package or sachet of the

subject invention consisting of three layers and enclosing an intravaginal ring, the contents of which are prevented to leak to the environment. That is, none of the cited references discloses a package with the limitations set forth in the claims, namely a package comprising a laminate and a reclosable strip in which the laminate consists of a layer of sealable material, a barrier layer and a damage protective layer.

Therefore, Igarishi in view of JP 7-223653 does not render claims 1-5 and 7-10 obvious. Withdrawal of this rejection is requested.

Claim 6 was rejected under 35 U.S.C. § 103(a) as being obvious over Igarashi (US 4,997,653) in view of JP 7-223653 and further in view of Higuchi et al. (US 3,995,631). The Examiner contends that it would have been obvious to use the laminated bag of JP 7-223653 for the vaginal ring of Igarashi and substituting PET of Higuchi et al. for the polyethylene of JP 7-223653. It is submitted that the Examiner is in error in this rejection.

In reply, the deficiencies of Igarishi and JP 7-223653 as discussed above, are not remedied by Higuchi et al. which does not at all relate to the field of packaging, let alone of packaging intravaginal rings. Higuchi et al. relates to the field of osmotic dispensers (which, e.g., can be fabricated in the form of a vaginal ring).

Higuchi et al. does not suggest anything about the packaging of intravaginal rings, let alone of the problem of leakage of active ingredients from the ring to the environment. Therefore, there was no incentive whatsoever to combine Higuchi with Igarishi and/or JP 7-223653.

Even if, in arguendo, one were to combine Igarishi with JP 7-223653 and with Higuchi et al., one would still not arrive at the package of claim 6 since the package of the subject invention consists of 3 layers only, not at least four as disclosed by JP 7-223653. That is, none of the cited references discloses a package with the limitations set forth in the claims, namely a package comprising a laminate and a reclosable strip in which the laminate consists of a layer of sealable material, a barrier layer and a damage protective layer.

Application Serial No. 09/555,459  
Amendment dated 14 January 2005  
Reply to Office Action mailed 14 October 2004


Thus, Igarishi in view of JP 7-223653 and further in view of Higuchi et al. does not render claim 6 obvious. Withdrawal of this rejection is requested.

Applicants note that the present application corresponds to European patent application number 98963567.7. The corresponding European application has been granted as patent number EP 1 037 812 B1. A copy of this granted patent is attached for the convenience of the Examiner. Applicants note that this patent was granted over art cited by the present Examiner, specifically Igarishi (see attached family list showing EP A 0 330 768 corresponds to US 4,997,653) and JP 7-223653.

In view of the above amendment and remarks, it is believed that the claims satisfy the requirements of the patent statutes and are patentable over the prior art. Reconsideration of the instant application and early notice of allowance are requested. The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

Respectfully submitted,

ROTHWELL, FIGG, ERNST & MANBECK, p.c.

By \_\_\_\_\_  
Jeffrey L. Ihnen  
Registration No. 28,957  
Attorney for Applicants  
1425 K Street, N.W., Suite 800  
Washington, D.C. 20005  
Telephone No.: (202) 783-6040  
Facsimile No.: (202) 783-6031

Attachments: FR 2 748 994  
EP 1 037 812 B1  
Family List for EP 0 330 786

118A.am4.wpd